

activated charcoal that removes odors-smoke-fumes and bacteria-SKF-16" x 25" x 1".

ACCOMPANYING LABELING: Leaflets entitled "Instruction Sheet," "Increase Your Profit," and "Dustronic Air Cleaners"; catalogs entitled "Dustronic Air Filters"; charts entitled "Atmospheric Contaminants Chart"; reprints entitled "Dust-Free Air for Your Home," "What's as Rare," "Ozone has Fresh Air Smell," "How Much Ozone Can You Take?," "Ions Affect Health, Behavior," and "Negative Ions for Everybody"; booklets entitled "Lectric Aire" and "You Can Relieve Hay Fever and Asthma"; testimonial letters from "Meridian Brick Co.," "Park Ridge School," "Herald Express," and "The Cove Realty"; circulars entitled "Banish Air Pollution" and "Increase Your Profit"; testimonial letters from "Department of Chemistry"; reprints entitled "Beware of Ozone" and "Mechanical Maid"; circulars entitled "Dealers Profits from Pure Aire"; catalogs entitled "Housewives! Enjoy More Leisure Time"; circulars entitled "The Facts and Figures"; leaflets entitled "Enjoy a Cleaner, Fresher, Healthier Home"; price lists entitled "Dustronic Air Filters"; and circulars entitled "What Dustronic Means To You" and "Medical Benefits from Activated Charcoal Air Purification."

RESULTS OF INVESTIGATION: The devices consisted of various combinations of the following basic elements: a motor-driven fan, an aluminum mechanical filter, an electrostatic filter, a charcoal filter, a high voltage power supply, and a negative ion generator (tritium disc). In use the devices reportedly filtered the room air, subjected it to increased negative ions, and recirculated the air back into the room.

The circulars entitled "What Dustronic Means To You" were prepared by Joseph F. Taraba, Seattle, Wash., who was a distributor for the devices, and the circulars entitled "Medical Benefits from Activated Charcoal Air Purification" were obtained by the dealer from Barnebey-Cheney Co., Columbus, Ohio.

The other accompanying labeling was supplied by the Radex Corporation.

LIBELED: 10-21-60, W. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving hay fever, asthma, sinus, migraine headaches, avoiding common colds and removing bacteria, eliminating air-borne allergies, reducing respiratory disorders, viruses, and bacteria, collecting "more than 99% of ragweed pollen" and irritating agents, reducing pains of burns, reducing high blood pressure, improving mental attitude, arresting cancer growth, reducing arthritis and rheumatism, slowing aging process, and reducing fungus infection.

DISPOSITION: 2-6-61. Consent—claimed by Radex Corp., and relabeled.

6440. Pasitabs. (F.D.C. No. 44915. S. No. 44-175 R.)

QUANTITY: 25 cases, 24 18-tablet btls. each, and 1 case of 24 36-tablet btls., at Seattle, Wash.

SHIPPED: Between 8-8-60 and 8-29-60, from Los Angeles, Calif., by Retail Drug Service.

LABEL IN PART: (Btl.) "Pasitabs Has a Tranquillizer Action—An Aid to Relieve Excitability * * * Caltex Distributors Inc. * * * Each tablet contains: Sodium and Ammonium Bromides 4.75 gr., Niacinamide 5 mg. Thiamine HCl (Vit. B₁) 1 mg. in a specially prepared base containing Extract of Jamaica

Dogwood, Pleurisy Root, Glycyrrhiza Extract, Humulus, Lupulus, Valerian Root."

ACCOMPANYING LABELING: Display cartons reading "Pasitabs * * * The Wonderful Non-Habit Forming Tablets with the Tranquilizer Action"; window posters reading "Do You Have Jittery Nerves or Normal Nerves?"; and window streamers reading "Pasitabs * * * Tranquilizer * * * Relieve Excitability."

LIBELED: 9-28-60, W. Dist. Wash.; amended libel 10-4-60.

CHARGE: 502(a)—when shipped, the labeling of the article was false and misleading since it contained statements which represented and suggested that the article was a "tranquilizer," whereas it was not adequate and effective as a tranquilizer, and it was not a true tranquilizing drug; and the labeling also contained false and misleading representations that the article was an adequate and effective treatment for jittery nerves, nervous tension, nervous headaches, nervous stomach, emotional upsets, and that it could help steady and soothe jangled nerves, and relieve excitability.

DISPOSITION: 11-23-60. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6421 TO 6440

PRODUCTS

	N.J. No.		N.J. No.
Amphetamine capsules-----	6423, 6424	Lumbago, remedy for. <i>See</i>	
tablets-----	6423, 6424	Rheumatism, remedy for.	
Arthritis, remedy for. <i>See</i>		Metabolin capsules-----	6434
Rheumatism, remedy for.		Neuralgia, remedy for. <i>See</i>	
Barbiturate capsules-----	6424	Rheumatism, remedy for.	
tablets-----	6424	Neuritis, remedy for. <i>See</i> Rheu-	
Bursitis, remedy for. <i>See</i> Rheu-		matism, remedy for.	
matism, remedy for.		Pasitabs -----	6440
Cancer, remedy for-----	6421	Phyltone capsules-----	6422
Cannolene scalp ointment-----	6426	Pro-Lecin tablets-----	6432
tetter salve-----	6426	Prophylactics, rubber-----	6429, 6430
Complex Z.A.-----	6421	Pro-Vita tablets-----	6432
Cosmetics (subject to the drug		Rheumatism, remedy for-----	6435
provisions of the Act) --	6426, 6438	Sciatica, remedy for. <i>See</i> Rheu-	
Devices-----	6429, 6430, 6439	matism, remedy for.	
Dustronic Air Cleaner-----	6439	Secobarbital sodium capsules---	6427
Gastric ulcers, remedy for---	6431, 6437	Skin disorders, remedy for-----	6438
Hair and scalp preparations_	6426, 6438	Tetter salve-----	6426
Hemasthesia ointment-----	6435	Ulcers, remedy for-----	6431, 6437
Hemorrhoids, remedy for-----	6435	Ulcertrol -----	6431
Higadoce Forte injection-----	6428	Ul-C-Eze -----	6437
Honegar -----	6436	Virilon Hair Follicle Cleanser---	6438
Laxative without required warn-		Physician's Formula-----	6438
ing statement-----	6425	Vita-Lea tablets-----	6432
Lecithin granules-----	6433	Vitamins -----	6428
Lectric Aire Negative Ionizer---	6439	W & S Protein 90-----	6425
L6 tablets-----	6435		

U.S. Department of Health, Education, and Welfare**FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6441-6460

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered by default, or by consent, and in one case by consent after compliance with a court order directing the claimant to supplement its answers to Government interrogatories; (2) criminal proceedings which were terminated upon pleas of guilty or nolo contendere; and (3) an injunction proceeding terminated upon the entry of a permanent injunction by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs*.

WASHINGTON, D.C., September 27, 1961.

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*For omission of, or unsatisfactory, ingredients statements, See Nos. 6441, 6443; failure to bear a label containing an accurate statement of the quantity of the contents, No. 6443; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6441, 6443, 6456; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 6449.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. NOS. 6441-6460**

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia or National Formulary), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its quality fell below that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; Section 502(c), the article failed to bear on its label or labeling, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e) (1), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling; Section 502(l), the article was composed wholly or in part of bacitracin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b) (4), the article was a drug subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER
WHEN USED ACCORDING TO DIRECTIONS**

6441. Distilled water and hypodermic kits. (F.D.C. No. 45071. S. Nos. 31-110/2 R.)

QUANTITY: Unknown quantities of a clear liquid in unlabeled glass ampuls represented to be the *Koch Treatment*, and unknown quantities of hypodermic kits, each kit containing a glass hypodermic syringe and needle, at Palestine, Tex., in possession of Reynolds Clinic.

SHIPPED: On unknown dates from places outside the State of Texas.

ACCOMPANYING LABELING: Leaflets entitled "The Reynolds Clinic * * * Since 1941," "Koch's Glyoxylide 12X," "The Koch Treatment (Glyoxylide) in Alcoholic Neuritis * * * 3. Arthritis," "The Koch Treatment (Glyoxylide) in Alcoholic Neuritis * * * 2. Bursitis, Sciatica, Toxic Liver and Arthritis," "Order Form"; brochures entitled "Glyoxylide Case Reports" and "The Koch Treatment Patients Diet"; and a mimeographed slip of paper reading in part "Glyoxylide 12X Sterile * * * O=C=C=O."

LIBELED: 11-2-60, E. Dist. Tex.

CHARGE: *Clear liquid in ampuls.* 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that